## REMARKS

Entry of the foregoing, reexamination and reconsideration of the subject application are respectfully requested in light of the amendments above and the comments which follow.

As correctly noted in the Office Action Summary, claims 1-16 and 23-46 were pending, with claims 23-40 being withdrawn from consideration. By the present response, claim 1 has been amended. Thus, upon entry of the present response, claims 1-16 and 41-46 are pending and await further consideration on the merits.

Support for the foregoing amendments can be found, for example, in at least the following locations in the original disclosure: [0045], [0063], [0103], [0104], Figure 1B, and the original claims.

Entry of the forgoing is appropriate pursuant to 37 C.F.R. §1.116 for at least the following reasons. First, the amendments raise no new issues that would necessitate further search and/or substantive reexamination. Second, the amendments clearly overcome the grounds of rejection.

### *CLAIM REJECTIONS UNDER 35 U.S.C. §102*

Claims 1-14 and 16 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,702,716 to Dunn et al. (hereafter "*Dunn et al.*") on the grounds set forth on page 2 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

The present invention is directed to an implant that can easily and quickly be shaped *in situ* or *ex situ* into a desired form, and can promote growth and generation

of bone tissue. A composition formed according the principles of the present invention is set forth in amended claim 1. Amended claim 1 recites:

> *1. A moldable implant composition for use in repairing a bone defect in a living organism, comprising:*
> *a plurality of biocompatible synthetic non-polymeric granules, said granules constituting a major fraction of said implant composition and having an equivalent diameter of about 100 μm to about 4,000 μm;*
> *a biocompatible polymer on at least a portion of said granules so as to form an implant mass comprising said granules and said biocompatible polymer, said biocompatible polymer comprising about 4% to about 20% of the total weight of the implant mass; and*
> *a plasticizer in said implant mass in an amount sufficient to condition at least a portion of said biocompatible polymer so that said implant mass is initially plastically deformable into a desired shape and then hardenable upon removal of at least a portion of said plasticizer from said implant mass.*

Dunn et al. is directed to a system for controlled release of biologically active materials, and to a liquid composition for its formation. Dunn et al. discloses that the system and liquid described therein comprises a polymeric matrix. See, e.g. col. 3, lns. 58-60. The polymer matrix may contain a bioactive material disposed within, and capable of being released from, the polymer matrix. See, e.g. col. 10, lns. 6-9. Dunn et al. further discloses that:

> The bioactive material can be miscible in the polymer. . .
> to form a suspension or dispersion with the polymer. . .
> the biologically active material becomes incorporated into
> the polymer matrix. (Col. 11, lns. 21-27)

By contrast, as readily apparent from the above, the composition of claim 1 requires, *inter alia*, granules which constitute a major fraction of the implant composition. By contrast, the bioactive materials which the grounds for rejection assert correspond to the recited synthetic non-polymeric granules clearly do not constitute a major fraction of the implant composition. To the contrary, as made

abundantly clear by the above-quoted disclosure of Dunn et al., such materials constitute a minor fraction of the overall composition so as to form a dispersion within the polymer matrix. Thus, Dunn et al. fails to disclose at least this aspect of the composition of claim 1. In addition, claim 1 also specifies that the biocompatible polymer comprises about 4% to about 20% of the total weight of the implant mass. By contrast, Dunn et al. contains no such corresponding disclosure.

Thus, for at least the reasons set forth above, Dunn et al. fails to anticipate the composition set forth in amended claim 1.

The remaining claims depend from claim 1. Thus, these claims are also not anticipated by the disclosure of Dunn et al. for at least the same reasons noted above in connection with the discussion of amended claim 1.

Claims 1-16, 41, 43, 44 and 45 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,241,316 to Evans et al. (hereafter "*Evans et al.*") on the grounds set forth on page 2 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

In addition to the composition as defined by amended claim 1, which is reproduced above, the present invention is also directed to a composite implant mass and composite matrix as set forth in claims 41 and 43, respectively:

> *41. A composite implant mass comprising:*
> *a structural component, the structural component comprising a plurality of biocompatible synthetic non-polymeric granules;*
> *a biocompatible polymer on at least a portion of the granules; and*
> *a plasticizer in an amount sufficient to condition at least a portion of the biocompatible polymer so that the implant mass is initially plastically deformable.*

*43. A composite matrix comprising:*
*a structural matrix, the structural matrix comprising a plurality of biocompatible synthetic non-polymeric granules bound together, at least in part, by a biocompatible polymer; and*
*an open porous region comprising spaces or discontinuities between adjacent granules.*

Contrary to the assertions contained on pages 2-3 of the Official Action, *Evans et al.* fails to anticipate, or suggest, the composition, composite mass or composite matrix of claims 1, 41 and 43 of the presently claimed invention.

*Evans et al.* is directed to devices and methods for treating defects in the tissue of a living organism comprising collagen and other bio-reabsorbable materials. See, e.g. the Abstract of *Evans et al.*

It is asserted in the grounds for rejection that the "biocompatible nanoparticles" described by *Evans et al.* corresponds to the granules of the presently claimed invention. However, with respect to claim 1, amended claim 1 requires that the implant composition comprise granules which constitute a major fraction of the implant composition and have an equivalent diameter of about 100 μm to about 4,000 μm. By contrast, "nanoparticles" have a size dimension which are several orders of magnitude smaller than the claimed 100 μm to 4,000 μm granules. Thus, the disclosed nanoparticles in *Evans et al.* fail to disclose the granules recited in amended claim 1. In addition, it is noted that given the small size of the nanoparticles described by *Evans et al.*, and their function within the implant, it would appear that such nanoparticles do not constitute a major fraction of the overall weight of the composition. In addition, amended claim 1 requires the presence of a biocompatible polymer comprising about 4% to about 20% of the total weight of the implant mass. By contrast, *Evans et al.* contains no such disclosure.

Various portions of the *Evans et al.* disclosure is referenced in the grounds for rejection. However, none of the identified portions of the *Evans et al.* disclosure support a finding of anticipation at least with respect to amended claim 1. Specifically, Figures 15-18 illustrate an implant having a fibrous collagen matrix (not synthetic non-polymeric granules); column 16, lines. 20-61 describe the incorporation of various "cellular additions" to the implant; column 18, lines 63-67 simply refer to the use of plasticizers in the implant composition; and columns 19-20 described the aforementioned nanoparticles which are not believed to satisfy the recited granules of amended claim 1.

For at least the reasons explained above, *Evans et al.* fails to anticipate the composition of amended claim 1.

Claims 41 is directed to a composite implant mass comprising a structural component, which in turn comprises a plurality of biocompatible synthetic non-polymeric granules. By contrast, *Evans et al.* discloses the use of nanoparticles, primarily as additives to a polymer matrix type material. Thus, the identified nanoparticles described by *Evans et al.* do not constitute a structural component of the implant mass. Thus, *Evans et al.* fails to anticipate claim 41.

Claim 43 is directed to a composite matrix which comprises a structural matrix, which in turn comprises a plurality of biocompatible synthetic non-polymeric granules. Again, the nanoparticles described by *Evans et al.* do not form a structural matrix. Thus, *Evans et al.* clearly fails to anticipate the composite matrix recited in claim 43.

The remaining claims depend either directly or indirectly upon claims 1, 41 or 43. Thus, these claims are also not anticipated by *Evans et al.* for at least the same reasons explained above.

***CLAIM REJECTIONS UNDER 35 U.S.C. §103***

Claims 42 and 46 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Evans et al.* on the grounds set forth on page 3 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

It is alleged on page 3 of the Official Action that the weight percentages of the biocompatible polymer constituent of the implant mass recited in claims 42 and 46, although admittedly not disclosed in any manner whatsoever by *Evans et al.*, would nonetheless be obvious. In re Aller is cited in support of this conclusion. This assertion is respectfully traversed.

Contrary to the assertion contained the grounds for rejection that "the general conditions of a claim are disclosed in the prior art," *Evans et al.* clearly fails to disclose the "general conditions" of either claims 41 or 43. To the contrary, claims 42 and 46 specify that, with respect to the relative proportions of granules and a polymer contained in the materials, the granules of the present invention constitute the major constituent component thereof. *Evans et al.* contains no such disclosure of a composite material wherein synthetic non-polymeric granules constitute a major fraction with respect to a biocompatible polymer constituent. Thus, *Evans et al.* clearly fails to disclose such "general conditions." That being the case, there is no basis to assert that the recited proportions of polymeric components is simply "discovering the optimum or workable ranges." To the contrary, *Evans et al.* suggest that the organic or polymeric constituent components of the composite materials

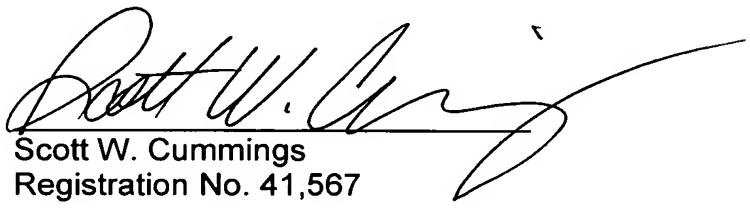
described therein should constitute a relatively larger portion of the overall weight of the composite materials of *Evans et al.*, and thus teaches away from claims 42 and 46. Therefore, claims 42 and 46 are also non-obvious over the teachings of *Evans et al.* for at least the reasons explained above. Reconsideration and withdrawal of the rejection is respectfully requested.

***CONCLUSION***

From the foregoing, further and favorable action in the form of a Notice of Allowance is earnestly solicited. Should the Examiner feel that any issues remain, it is requested that the undersigned be contacted so that any such issues may be adequately addressed and prosecution of the instant application expedited.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: October 3, 2008 By: 

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